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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,080	12/18/2000	Michael Thomas Lee	P-8788	4542

27581 7590 10/01/2002

MEDTRONIC, INC.  
710 MEDTRONIC PARKWAY NE  
MS-LC340  
MINNEAPOLIS, MN 55432-5604

EXAMINER

BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/740,080

Applicant(s)

LEE ET AL.

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2000.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claim 21 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 21 is combination of claim 1 and claim 13.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Arguments***

2. Applicant's arguments filed July 9, 2002 have been fully considered but they are not persuasive. The arguments are moot in view of new grounds of rejection by amendment.

In response to the Applicant that the Examiner is using the principles of inherency incorrectly, in the alternative the Examiner has cited a reference that "analyzes physiologic data according to a physiologic model". It is inherent that a comparison is made to a model in order to change parameters, see Scarantino et al. U.S. Patent No. 6,402,689.

Also in further review of the Thompson et al. reference, Thompson is able to acquire data from more than one implantable medical device and is transmitted to a centralized computing resource and analyzed (Fig. 1 or Fig. 3). Since claims 1 and 14 have been rejected, all subsequent rejections stand.

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***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claim 13, what is the complex linear analysis that is being performed?

***Claim Rejections - 35 USC § 102/103***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-9 and 12, 14 and 15 rejected under 35 U.S.C. 103(a) as obvious over Thompson et al. U.S. Patent No. 6,083,248.

Referring to claims 1 and 14, Thompson states in column 15, lines 36-38 that data is transmitted back to the support network for analysis. Therefore, it is inherent that a comparison is made to a model in order to determine how to change the parameters.

In the alternative Thompson discloses the claimed invention except for analyzing physiologic data according to a physiologic model. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computerized method as taught by Thompson, by analyzing physiologic data according to a physiologic model since it is well known in the art to compare models to change parameters.

### **Claim Rejections - 35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2 and 12 are rejected under 35 U.S.C. 103(a) as obvious over Nappholz et al. U.S. Patent No. 5,720,770 in view of Thompson et al. U.S. Patent No. 6,083,248.

Referring to claim 1, Nappholz discloses steps of:

- transporting via a network communication link data gathered from at least one IMD to a computing resource external to any patient (14)
- analyzing the physiologic data according to a suitable model (inherent)
- determining instructions of the IMD based on the results of the analysis of the physiological data (column 7, lines 59-62)
- transmitting via a network communication link the instructions for execution (14).

But Nappholz fails to disclose wherein physiologic data is acquired from at least two implantable devices. However, Thompson discloses wherein physiologic data is acquired from at least two implantable devices (10) as a means for acquiring and monitoring more parameters.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Nappholz wherein physiologic data is acquired from at least two implantable devices, as taught by Thompson, as a means of acquiring and monitoring more parameters.

Referring to claim 2 wherein the network communication link comprises a radio frequency link (24).

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Referring to claim 12, wherein one or more IMDs comprises one or more of a pacemaker (12).

It is inherent that a comparison is made to a model in order to determine how to change the parameters. In the alternative Nappholz discloses the claimed invention except for analyzing physiologic data according to a physiologic model. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computerized method as taught by Nappholz, by analyzing physiologic data according to a physiologic model since it is well known in the art to compare models to change parameters.

10. Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. U.S. Patent 5,720,770 in view of Thompson et al. 6,083,248.

Referring to claims 3-9 Nappholz fails to teach the methods of wherein the network communication link comprises a hybrid link, the hybrid communication comprising a radio frequency and a secondary link to a central computing resource, the secondary link is direct dial up connection, the secondary network link is an area network, the area network is a LAN, the area network is a WAN, and the area network is one of internet, intranet, extranet or world wide. However, Thompson teaches the methods of wherein:

- the network communication link comprises a hybrid link (column 5, lines 47-56) as means to better establish connection

- the hybrid communication comprising a radio frequency and a secondary link to a central computing resource (Fig 2) to have an alternate means to communicate with the central computer if one way happens to fail
- the secondary link is direct dial up connection (column 15, line 7) as an alternate means to communicate with the central computer
- the secondary network link is an area network (column 14, lines 55 and 56) as means to link computers together
- the area network is a LAN (column 14, line 56) as means to link computers together locally
- the area network is a WAN (column 1, lines 12 and 13) as a means to link computers together in various locations.
- the area network is one of internet, intranet, extranet or world wide (column 4, lines 64-67) as means of having various network systems.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Nappholz with the methods wherein the network communication link comprises a hybrid link as means to better establish connection, the hybrid communication comprising a radio frequency and a secondary link to a central computing resource to have an alternate means to communicate with the central computer if one way happens to fail, the secondary link is direct dial up connection as an alternate means to communicate with the central computer, the secondary network link is an area network as means to link computers together, the area network is a LAN as means to link computers together locally, the area network is



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a WAN as a means to link computers together in various locations, and the area network is one of internet, intranet, extranet or world wide as means of having various network systems.

11. Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (or Nappholz) as applied to claim 4 and 14 above, and in further view of Varrichio et al. U.S. Patent No. 5,186,170.

Referring to claims 10 and 19, Thompson (or Nappholz) fails to teach a network communication link that is asynchronous. However, Varrichio teaches a network communication link that is asynchronous (column 1, line 60) as a means to allow communication of data one way at a time.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Thompson (or Nappholz) with a network communication link that is asynchronous, as taught by Varrichio, as a means to allow communication of data one way at a time.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (or Nappholz) as applied to claims 4 and 14 above, and further in view of Deschamp et al. U.S. Patent No. 5,899,931.

Referring to claim 11, Thompson (or Nappholz) fails to teach a network communication link that is synchronous. However, Deschamp teaches a network communication link that is synchronous (column 2, lines 30-32) as a means to allow communication of data simultaneously.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Thompson (or Nappholz) with a network communication link that is synchronous, as taught by Deschamp, as a means to allow communication of data simultaneously.

13. Claim 16-18 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nappholz et al. U.S. Patent No. 5,720,770.

Referring to claims 16-18, Nappholz discloses the claimed invention except for the super computer, multi-processor workstation, and networked cluster of computers. It would have been an obvious matter of design choice to use a super computer, multi-processor and networked cluster of computers, since the applicant has not disclosed that a super computer, multi-processor or networked cluster of computers solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any computer, such as the database as taught by Nappholz for processing and analyzing data.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*R. Bradford*

R.B. 9/23/02  
September 23, 2002

*Angela D. Sykes*

ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700